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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
08/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	09/772,445	KLEINMAN ET AL.	
	Examiner	Art Unit	
	Ronald T. Niebauer	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40,53-61 and 133-136* is/are pending in the application.

4a) Of the above claim(s) *9,10,12,20,21 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13-19,22-36,38-40,53-61 and 133-136* is/are rejected.

7)☒ Claim(s) *39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/7/06,3/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to the contact information listed at the end of this office action.

Response to Amendment/Arguments

Applicant's amendments and arguments, filed 2/7/06 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 41-52,62-132,137-172 are cancelled. Claims 9-10,12,20-21,37 are withdrawn as being drawn to non-elected subject matter.

Applicants argue that particular claims should be rejoined. However, rejoinder is considered when all the claims directed to the elected invention are in condition for allowance (MPEP section 821.04). Since no claims are in condition for allowance, rejoinder has not been considered.

Claim Objections

Claim 39 is objected to because of the following informalities: claim 39 recites "issue" on the first line wherein the word should be --tissue--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8,11,23-36,38-40,133-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been

placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to methods comprising administering a polypeptide or a conservative variant having wound-healing activity.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high with regard to methods of wound healing. The level of knowledge in the art is low regarding understanding the functional effects of varying a particular peptide sequence given that the effects of substitutions cannot be predicted a priori.

(2) Partial structure:

A conservative variant is defined (page 11), however specific examples of the many variations are not provided. There are hundreds of possible polypeptides that fall within the scope of the claims. Since there are a substantial variety of polypeptides possible within the genus, the limited examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see *Gostelli* above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The peptides and variants are recited as having wound-healing activity. There is no disclosed correlation between this functional characteristic and any structure. One of skill in the art would not recognize which variants are sufficient to have wound-healing activity and one could not a priori predict the properties.

(5) Method of making the claimed invention:

Methods of making peptides are well known in the art, however given the unpredictable nature of amino acid substitution methods of making peptides and peptide variants such that the peptides maintain wound-healing properties is not well established.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1,23 is/are broad and generic, with respect to all conservative variants encompassed by the claims. The possible structural variations are numerous to any variant. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description peptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1-8,11,23-36,38-40,133-136 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoting wound-healing with specific peptides in vivo for the cornea and skin, does not reasonably provide enablement for methods of

making and using any peptide variants for any type of wound healing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

In the instant case, the claims are drawn to methods comprising administering a polypeptide or a conservative variant having wound-healing activity. The wounds are associated with eye, skin, uro-genital, gastro-intestinal, cardiovascular, muscle, connective, neural tissues, or healing of any and all wounds associated with diseases or conditions selected from arthritis, osteoporosis, musculo-skeletal disorders, bums, skin diseases, neurodegenerative disorders, nerve diseases, bone diseases, heart disease, retinal damage, all skin damage, cardiovascular diseases, an ischemia, atherosclerosis, fibrotic disorder, sclerotic disorder, cancer and all cell proliferative disorders

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The claims are drawn to conservative variants which include amino acid substitutions. However, the knowledge in the art is low with regard to understanding which amino acid sequences will have a particular function given that the effects of substitutions cannot be predicted a priori. With regards to the effect of amino acid substitution in a peptide or protein, the art is unpredictable.

MATHISON (US Patent 6,586,403 B1) teaches that "Restriction on the amino acid substitutions that are tolerated in analogues of FEG/feG are described [...] although a theory for the rational substitution of amino acids in to the peptides that permits the prediction of biological activity of specific peptides is not apparent. For example, it is not obvious which aromatic or aliphatic substitutions in position 1 of tri- or dipeptides would possess biological activity in the four assays examined" (column 12, lines 22-30).

Further, MPEP § 2144.08 states, "The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior domains. James Darnell *et al.*, *Molecular Cell Biology* 51 (2d ed. 1990)."

(5) The relative skill of those in the art:

The level of skill in the art is high regarding wound healing in general, however, the knowledge in the art is low with regard to understanding which amino acid sequences will have a particular function given that substitutions cannot be predicted a priori.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

Examples (such as example 1) are provided in which a specific peptide is tested for wound healing functionality. However, the specification does not provide examples for the breadth of the peptide variants possible. Further, examples of making specific variants with wound-healing properties have not been provided. Specifically, one of skill in the art would not accept that all variants described would function in wound healing.

(8) The quantity of experimentation necessary:

Experimentation is required in numerous areas particularly related to how to make specific variants with wound healing properties and determination if it would be a useful composition against the plethora of associated conditions. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3,5-7,11,13-14,16-18,22-29,33-36,38-39,53-55,57-59,61,133-135 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann (US 6,030,948). It is noted that the 102(e) date for Mann is Dec. 19, 1997 based on MPEP section 706.02(f)(1) section III for a patent that is not from an international application and in which there is no international application in the continuity chain.

Briefly the claims are drawn to methods comprising administering/contacting with a particular composition. Section 2111.02 of the MPEP states:

> During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963)

In the instant case, limitations such as promoting migration (claim 53) do not result in a manipulative difference and do not serve to limit the claims.

Mann teach a composition (claim 1, Tables 13-16) containing thymosin fraction 5. The thymosin fraction 5 includes both thymosin β4 (which comprises the sequence LKKTET) and thymosin α1 (which itself can augment the wound healing process – see page 11 of specification of the current invention). Mann teach a method of applying this composition to the scalp (claim

8). Prior to application to the scalp, an acid peel (i.e. chemical peel) solution is applied to the scalp and then removed. The removal of the acid peel solution results in the removal of an outer layer of the skin and results in abrasion/damage/lesions/wounds on the skin. Mann teach that the composition can be applied topically as a lotion or gel (column 3) and can be used for males or females (Tables 13-16). Since the composition is applied to the skin it is applied to a tissue and specifically to epithelial cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4,8,15,19,30-32,40,56,60,136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann (US 6,030,948), Siebert et al. (US 5,591,716), Luedders et al. (US 4,261,982), and Rahim et al. (US 4,863,906).

Briefly the claims are drawn to methods comprising administering/contacting with a particular composition.

As stated above, Mann teach methods of administering a composition comprising thymosin β4.

Mann does not expressly teach thymosin as a recombinant or synthetic peptide (claim 8,19 of the current invention), contacting *in vitro* or *ex vivo* (claim 6), the use of a specific component such as sterile water recited in claim 136, the use of transforming growth factor beta (claim 4 for example), the use of zinc (claim 32 for example), or the use on the eye (claim 40 for example).

It is well-known in the art that a recombinant peptide can be substituted for a purified peptide while maintaining an expectation of predictable results since the primary sequence of the protein is retained. Similarly, the substitution of sterile water for water is well-known. Hence, it would have been obvious to one of skill in the art to substitute one component for the other to achieve a predictable result since the active component (thymosin) is still present.

Regarding contacting *in vitro* or *ex vivo*, since *in vivo* work is suggested by Mann, it would be obvious to one of skill in the art to try and determine if similar results could be obtained *in vitro* so that experimental results could be achieved in a more cost effective manner in a laboratory setting instead of requiring human subjects.

As stated above, Mann teach methods of administering a composition comprising thymosin β4. Siebert teach a composition comprising TGFβ for wound healing (claim 8, column 18). Since all of the prior art elements were known in the art one of skill in the art would have combined the elements for the same purpose (wound healing) and the combination would have yielded predictable results.

As stated above, Mann teach methods of administering a composition comprising thymosin β4. Luedders teach a composition (for example claim 5) including zinc ions for topical application to the skin. Leudders teach that zinc has been linked to wound healing (column 1). Since all of the prior art elements were known in the art one of skill in the art would have combined the elements for example, to enhance the wound healing process, and the combination would have yielded predictable results since the active component (thymosin) is still present.

As stated above, Mann teach methods of administering a composition comprising thymosin β4. Rahim teach a therapeutic composition (column 6) including thymosin which can be administered to the eye (column 5). Since all of the prior art elements were known in the art one of skill in the art would have combined the elements and the combination would have yielded predictable results since the active component (thymosin) is still present.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the

references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The examiner has identified three copending Applications/Patents which have been rejected under Double Patenting. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Claims 1-3,5-8,11,13-14,16-19,22-25,27-29,33-36,38-39,53-55,57-59,61,133-135 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10-12 of copending Application No. 10/714,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '405 application teaches methods of treating/healing of blisters, sores or skin degeneration (which are wounds) by application of proteins comprising the LKKTET sequence or Thymosin beta four. The methods encompass systemic and topical application of the compositions, to include the instantly claimed formulations (gel, crème, paste, lotion, spray, suspension, dispersion, salve, hydrogel, or ointment). Additionally, the '405 application claims teach administering an agent that stimulates the proteins comprising the LKKTET sequence or Thymosin beta four as in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7,13-18,23-28,30,33-36,39,53-55,57-59,61,133-135 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-16 of copending Application No. 11/284,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '408 application teaches methods of administering compositions to the skin comprising thymosin beta four (for example, claim 7), transforming growth factor (claim 8), for topical treatment (for example, claim 7).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8,11,13-19,22-36,38-40,53-61,133-136 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over allowable claims 3-8,29-35 (which have been indicated as allowable 3/29/07) of application 10/853,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because '505 teach a composition comprising thymosin beta four (claim 5) and the since the specification is the same as that of the current invention one having ordinary skill in the art would have been motivated to use the particular combinations and methods recited in the specification and have expectation for success.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/714,405; 11/284,408; 10/853,505; discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600